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EXAMINER

MAI, HAO D

ART UNIT

PAPER NUMBER

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. **Claims 128-133, 145, and 147-149, are rejected under 35 U.S.C. 103(a) as being unpatentable over Taylor et al. (6,036,641).**

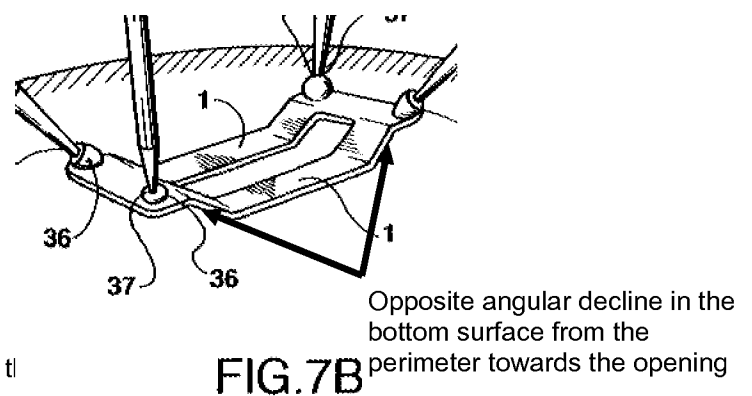
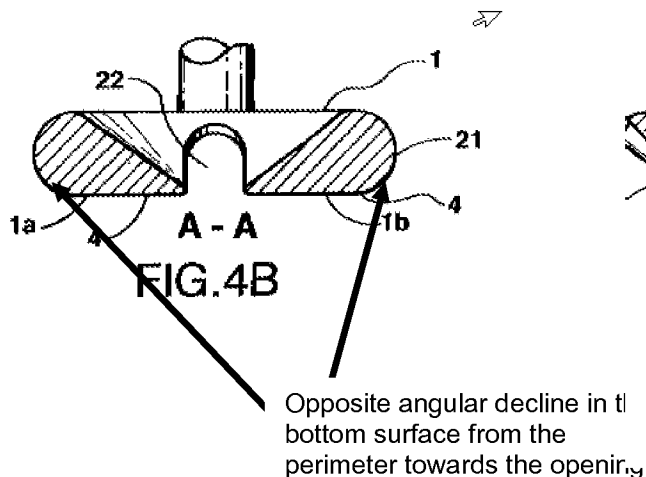
Regarding claims 128, Taylor et al. disclose a device 1 (refer to Fig. 9A) capable of providing additional stabilization to tissue already in contact with a primary stabilization member, the device comprising: a single, substantially rigid tissue contact member 1 formed as a unitary U-shaped loop capable of being placed on the tissue; and a connecting member/handle integrally formed with and extending from the tissue contact member and capable of being hand held or fixed to a relatively immovable object (Fig. 9A). The bottom surface of the contact member includes a contact surface that declines angularly in a radial direction from a periphery of said loop towards an opening (between the legs of the U-shaped loop) in the middle of said loop, i.e. the outer periphery that contains lumen 48/47 is shown to be thicker than the area toward to the center. Also see further reasoning with annotated drawings below regarding the angular decline in the bottom surface.

Taylor et al. disclose the invention substantially as claimed except for the loop being continuous. However, such continuous loop shape is well known in the surgical field. For example, in the embodiments of Figures 7B and 8, Taylor et al. show a contact member in the

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shape of a continuous loop. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the U-shaped loop of Figure 9A to be a continuous loop in order to establish a more stable contact between the contact member and the tissue. Furthermore, such modification is merely a change in shape that is well within the skill of a person in the art. MPEP § 2144.04.

Furthermore, Taylor et al. show in alternative embodiments of Fig. 4B and Fig. 7B various contact members wherein the bottom surface declines angularly in a radial direction from a periphery of said contact member towards an opening in the middle; wherein "such that said bottom surface is angled in opposite directions on opposite sides of said opening" as newly recited (see annotated drawings of Fig. 4B and Fig. 7B below). It would have been obvious to one having ordinary skill in the art at the time the invention was made to include such opposite angular decline in the bottom surface of the contact member so that the tissue contact area of the bottom surface would be minimum (i.e. at the lowest point of the angular decline) in order to prevent damage to the tissue.



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As to claims 129, the embodiments of Figure 9A, 7B, and 4B, each or the combination thereof has a base with central opening there through, capable of allowing access to a target site on the tissue. As to claims 130-131, such substantially oval-shaped, if not explicitly disclosed by Taylor et al., would have been an obvious design choice well within the skill of a person in the art. MPEP § 2144.04. As to claims 132-133, Figure 9A shows the base member having a substantially hollow interior (defined by lumen 48 extending through the base member as shown in Fig. 9A) capable of developing a negative or positive pressure therein; and said lumen 48 is in fluid communication with said base member (column 17; lines 30-42).

Regarding claims 145 and 147-149, Taylor et al. disclose all the claimed elements as detailed above with respect to claims 128-133.

3. Claim 134-137, 146, and 150, are rejected under 35 U.S.C. 103(a) as being unpatentable over Taylor et al. (6,036,641) in view of Borst et al. (5,836,311).

As to claim 134, Taylor et al. disclose the invention substantially as claimed including openings 47 being fluidly connecting with said substantially hollow interior (lumen 48) and capable of applying a negative pressure to the tissue (column 17 lines 30-42). However, Taylor et al. fail to disclose such openings being at the bottom surface of the contact member. Borst et al. disclose a base member 81 having substantially hollow interior and integral suction ports/openings 82 at the bottom surface thereof; the hollow interior and the suction ports/openings 82 are capable of developing and applying a negative pressure to the tissue (Fig. 13; column 7 lines 18-41). Figure 13 also shows a connecting member/handle being fluidly connected to the hollow interior of base 81 and is capable of being connected to a source of negative pressure (column 7 lines 18-35). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Taylor et al. by placing such suction ports/openings at the bottom surface in order to provide a suction mechanism that suck onto or

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seal with the tissues, providing a more effective stabilization of the heart as explicitly taught by Borst et al.

As to claims 135-137, Taylor et al. in Figure 9A disclose the base member having openings 47 through an upper surface thereof (Fig. 9A column 17 lines 40-42), and the openings 47 being connected to two different lumens 48. However, Taylor et al. fail to teach a source of pressure that is independent from a pressure in the hollow interior of said base member. Borst et al. disclose two separate independent suction sources (column 7 lines 29-34). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide Taylor et al. with two separate independent suction sources so that if one suction source were to lose contact with tissue, the other could still maintain capture as explicitly taught by Borst et al. (column 7 lines 29-34). Alternatively, one (negative) suction source can be used for adhering the contact member to the tissue as taught by Borst et al.; the other (negative or positive) suction source can be used for maintaining the surgical site clear and dry as taught by Taylor et al.

Regarding claims 146 and 150, Taylor et al. in combination with Borst et al. disclose all the claimed elements as detailed above.

Response to Arguments

4. Applicant's arguments regarding the amended claims have been fully considered but they are not persuasive and/or moot in view of the new ground(s) of rejection. Applicant's remarks are held to be responded to the above ground(s) of rejection. The newly recited claim language "such that said bottom surface is angled in opposite directions on opposite sides of said opening" fail to overcome Taylor et al.

Conclusion

5. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

6. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Any inquiry concerning this communication or earlier communications from the examiner should be directed to HAO D. MAI whose telephone number is (571)270-3002. The examiner can normally be reached on Monday-Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cris Rodriguez can be reached on (571) 272-4964. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

7. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

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system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

**/Hao D Mai/
Examiner, Art Unit 3732**

**/Cris L. Rodriguez/
Supervisory Patent Examiner, Art Unit 3732**